

REMARKS

Applicant acknowledges receipt of an Office Action dated May 13, 2008. Claims 22-41 remain pending in the application.

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

Rejection Under 35 U.S.C. § 102

On page 3 of the Office Action, the PTO has rejected claims 22 and 28 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 5,301,673 to Rabito et al. (hereafter "Rabito"). Applicant traverses this rejection for the reason set forth below.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See generally MPEP § 2131.

Here, Rabito fails to disclose the step of "simultaneously determining in vivo distributions of bioluminescent and/or fluorescent markers and radioactive markers" as recited in independent claim 22. Rabito also fails to disclose "alternately determining in vivo distributions of bioluminescent and/or fluorescent markers and in vivo distributions of radioactive markers with a common measurement apparatus" as recited in independent claim 28. Furthermore, Applicant notes that Rabito fails to disclose "determining in vivo distributions of bioluminescent and/or fluorescent markers and radioactive markers at identical projection angles" as recited in independent claim 22 and also fails to disclose "determining in vivo distributions of bioluminescent and/or fluorescent markers and . . . radioactive markers. . . at identical projection angles" as recited in independent claim 28. For at least these reasons, Applicant submits that the outstanding §102 rejection is improper and ought to be withdrawn.

Rabito is directed to and discloses a monitoring device with a detector for fluorescent *or* radioactive markers. Specifically, Rabito discloses that "in some preferred embodiments . . . the detector includes a radiodetector; or . . . the detector includes a photodetector." Rabito, Col. 3, lines 55-58 (emphasis added). Additionally, the "radiodetector can be a scintillator . . . or the detector can be a non-scintillating detector." Rabito, Col. 3, lines 59-61 (emphasis

added). Thus, Rabito teaches to select one substance and to use an appropriate detector. However, Rabito does not disclose, teach, or suggest using a combination of two detectors of different types as required by the presently claimed invention.

On page 2 of the Office Action, the PTO cites to Col. 15, lines 42-50 of Rabito and states that “Rabito teaches that two or more markers with different emission energies can be used simultaneously.” However, here Rabito is actually disclosing use of radioactive markers only, and not the use of fluorescent markers and photodetectors. Rabito states that “a plurality of substances ... detectable by different radiation energies; for example two or more filtration markers can be radiolabelled using labels having two different emission energies” for monitoring the functions of two or more organs. Rabito, Col. 15, lines 44-50. Rabito also discloses using multiple detectors and using a discriminator to resolve the signals. Rabito, Col. 15, line 67 – Col. 16, line 4. This passage of Rabito refers to radiolabelling only, particularly since a discriminator processing one single signal of one single source could not be used to distinguish fluorescent from radioactive labels. Therefore, Rabito discloses using a detector with a corresponding substance, i.e. a radiodetector and a radioactive substance, or, alternatively, a fluorescent substance with a light detector.

The specification of Rabito discloses embodiments for radiodetectors from column 6 to column 14, line 44, and embodiments for photodetectors from column 14, line 44 to the end. None of the described embodiments show the combination of a detector for fluorescent markers and a detector for radioactive markers. For example, from column 3, lines 21 to 38, it is obvious for persons skilled in the art that only one type of marker, *i.e.* a radio marker or a fluorescent marker, is used and that the detector is appropriately detecting only one kind of radiation, *i.e.* light or radioactive radiation. There is no disclosure of simultaneously using a radiodetector together with a photodetector for concurrently and separately detecting photons emitted by a fluorescent marker and photons emitted by a radioactive marker or using a radiodetector together with a photodetector in a common apparatus. Specifically, Rabito provides:

Column 6, lines 66-68	“radioactive substance and a radiodetector”
Column 7, lines 7-10	“An embodiment of the invention, namely a monitor adapted for measuring the clearance rate of a

	radiolabelled substance from the patient's extracellular fluid”
Column 7, lines 32-43	A “detector shielding layer 3 of lead about 2 mm thick” is disclosing the detection of radioactive markers only
Column 8, lines 1-4	“the detector is sensible substantially only to radiation reaching the detector”
Column 8, lines 22-24	“the data output signal from the radiation detector 4”
Column 8, lines 42-45	“a collection period 54 based upon the statistical estimate and corrects for dead time and isotope decay 55”
Column 9, lines 32-39	“A preferred label for use according to the invention is a radiolabel, and the corresponding detector is a radiation detector ... and the corresponding detector is a scintillation counting device such as ... a cadmium telluride or sodium iodide detector”
Column 9, lines 54-57	“The detector was a ... cadmium-telluride (Cd-Te) detector.”
Column 10, lines 40-48	Discusses renal scintigraphy using a gamma detector Gemini 700, General Electric
Column 10, lines 62-64	Relates to computer acquisition of the radioangiographic phase.
Columns 11-13	Relates to radiographic markers such as ⁵¹ Cr-EDTA or ^{99m} Tc-DTPA.

Furthermore, Rabito relates to the measurement of an amount of substance in order to derive the decrease of the substance over time (i.e. depletion or clearance), whereas the presently claimed invention relates to imaging, i.e. the detection of a two-dimensional distribution of substances. Throughout Rabito, the term “image” is exclusively used in connection with renal scintigraphy, i.e. the detection of radioactive radiation using a scintillation crystal transforming the radioactive radiation into optical photons, which are detected by a camera. It is obvious that in Rabito, the imaging is used for determining an

amount of marker and not to create a picture as a distribution of markers. See, Rabito, Col. 10, lines 48-52. Furthermore, as illustrated in Figures 1-3 of Rabito, the detection apparatus is placed directly on the surface of the object, which, in case of an optical detector, does not allow for the detection of an image. Rather, only the total intensity can be determined. For providing an image, a lens or a similar optical device would be necessary. Consequently, Rabito relates to the detection of an amount of substance in a volume, whereas the presently claimed invention relates to the detection of a distribution of a substance on a surface.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection under § 102.

Rejections Under 35 U.S.C. § 103

On pages 4-6 of the Office Action, the PTO has rejected claim 25 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rabito in view of U.S. Patent 6,232,107 to Bryan *et al.* (hereafter “Bryan”); claim 26 as allegedly being unpatentable over Rabito in view of U.S. Patent Application 2003/0101466 to Turner (hereafter “Turner”); claim 27 as allegedly being unpatentable over Rabito, in view of Turner, further in view of U.S. Patent 6,312,961 to Voirin *et al.* (hereafter “Voirin”); claims 23, 24, 29-34, and 36-41 as allegedly being unpatentable over Rabito in view of Turner, in view of Voirin, further in view of U.S. Patent 5,678,550 to Bassen *et al.* (hereafter “Bassen”); and claim 35 as allegedly being unpatentable over Rabito, in view of Turner, in view of Voirin, in view of Bassen, and further in view of U.S. Patent Application 2002/0042566 to Matsuzaki *et al.* (hereafter “Matsuzaki.”) Applicant traverses these rejections for the reasons set forth below.

The framework for the objective analysis for determining obviousness under §103 requires:

1. Determining the scope and content of the prior art;
2. Ascertaining the differences between the claimed invention and the prior art;
3. Resolving the level of ordinary skill in the pertinent art; and
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Teleflex, Inc. v. KSR Int'l Co., 127 S. Ct. 1727, 82 USPQ2d 1385 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

As outlined above, with respect to the rejections of independent claims 22 and 28, Rabito fails to disclose, teach, or suggest all of features of either claim 22 or claim 28. With respect to the dependent claims rejection under §103, the PTO has combined Rabito with various combinations of Bryan, Turner, Voirin, Bassen, and Matsuzaki. None of these references, taken either individually or in combination with Rabito, cures the fundamental deficiencies in Rabito outlined above.

In Bryan, the use of photoluminescence markers emitting in distinct wave-lengths is described. Bryan does not show the detection of radioactive markers. Rather, only fluorescence or luminescence markers are described.

While Turner relates to some radio markers, Turner does not describe any fluorescent markers. In particular, Turner does not relate to photo detection and consequently does not show the combined detection of light and irradiation of radio markers. Like Bryan, Turner only relates to one type of marker and consequently does not give any incentive to provide the combined detection of radio markers and fluorescent markers as defined in the claims of the present application.

Bassen describes an endoscope with a colour selective beam divider which divides the light emitted from the endoscope into an interference component and a fluorescent component, separating light of distinct color using a beamsplitter. In particular, Bassen discloses use of a dichroic filter. Bassen, Col. 5, lines 40-51. It is obvious for a person skilled in the art that a dichroic filter separates radiation of luminescent or fluorescent markers (optical radiation), and is not adapted to separate a first average energy of luminescent or fluorescent markers (light) from a second average energy provided by radioactive markers (gamma rays). A dichroic filter is not adapted for separating gamma rays from light. Thus, Bassen is based on the physical principle of chromatic separation of light, which fundamentally differs from the principle of separating light energy from gamma energy. For one skilled in the art, Bassen only describes separating one color from another, and does not teach or suggest a solution for separating fluorescent markers (light) from radioactive markers (gamma rays).

Voirin describes the separation of distinct wavelengths using a Bragg-filter. Voirin does not relate to radioactive markers or radioactive emissions and, consequently, does not disclose or render obvious the detection of radioactive markers.

In summary, none of the cited documents show the concurrent (temporally or within a common apparatus) detection of light and radiation emitted by radioactive markers. In contrast to the presently claimed method, the cited documents do not show (1) two distinct detectors for both, radioactive as well as for fluorescent markers in a common apparatus, (2) the concurrent detection of fluorescent and radioactive markers at the same point of time, or (3) the detection of fluorescent and radioactive markers at identical projection angles. The methods and devices described in the cited documents do not render obvious such a combination of two detectors for two different types of markers and cannot provide a superimposed image of a body region containing both, radioactive markers as well as fluorescent markers. Since fluorescent markers and radioactive markers have distinct properties and performance regarding resolution, sensitivity, permanence and selectivity regarding type of tissue, the combination of both detectors provides imaging and tomography results with significantly increased information content.

Since, none of the additional references does anything to resolve the fundamental deficiencies in Rabito, Applicant submits that no combination of these references can properly render either independent claim 22 or independent claim 28 obvious and that the dependent claims are non-obvious for at least the same reasons as their respective independent claims.

With regard to claim 29, it should be noted that Bassen and Voirin teach the separation of distinct optical wavelengths, in contrast to the apparatus of claim 29 which comprises a camera for light and a SPECT detector for radioactive irradiation. In particular, none of the cited documents describes or renders obvious a layer which reflects optical photons and transmits photons of radioactive markers. In comparison to the described Bragg-filters, such a layer can be provided with significantly reduced costs.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections under § 103.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 8/13/08
FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5540
Facsimile: (202) 672-5399

By P.D.S.
Paul D. Strain
Registration No. 47,369
Attorney for Applicant